TOBACCO CONTROL ACT PROGRAM

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2011 through FY 2013.

FDA Program Resources Table

(Dollars in thousands)

	FY 2011 Enacted	FY 2011 Actual	FY 2012 Enacted	FY 2013 Request	+/- Enacted
Program Level	**$421,463**	**$135,708**	**$454,751**	**$482,398**	**$27,647**
Center	$415,567	$134,145	$448,501	$472,998	$24,497
FTE	345	225	366	471	105
Field	$5,896	$1,563	$6,250	$9,400	$3,150
FTE	25	10	26	41	15
Program Level FTE	**370**	**236**	**392**	**512**	**120**
User Fees	**$421,463**	**$135,708**	**$454,751**	**$482,398**	**$27,647**
Center	$415,567	$134,145	$448,501	$472,998	$24,497
FTE	345	225	366	471	105
Field	$5,896	$1,563	$6,250	$9,400	$3,150
FTE	25	10	26	41	15
User Fees FTE	**370**	**236**	**392**	**512**	**120**

The FDA Tobacco Control Act Program operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399)
The Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31)
The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333)
Public Health Service Act of 1944 (42 U.S.C. 201)
Federal Advisory Committee Act (FACA) of 1972, as amended

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) oversees the implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA executes its regulatory and public health responsibilities in four subprograms:

- protecting the public health
- scientific standard-setting and product review
- compliance and regulation
- public education and outreach

FDA has three strategic priorities in implementing the Tobacco Control Act:

- decreasing initiation of tobacco product use;
- decreasing the harms of tobacco products; and
- encouraging cessation among tobacco product users.

To achieve its goals, FDA relies on its authorities to regulate the manufacturing, marketing, and distribution of tobacco products. Some of these authorities include:

- prohibiting tobacco product labeling or advertising or other marketing that is inaccurate, false, or misleading
- establishing tobacco product standards to protect the public health
- issuing Good Manufacturing Practice regulations for the manufacture of tobacco products
- requiring tobacco product manufacturers, importers, and distributors to register with FDA and requiring manufacturers and importers to provide a list of tobacco products they sell
- requiring industry reporting of tobacco product ingredient and constituent data,
- inspecting tobacco product establishments, including retailers, to assure compliance with existing FDA tobacco product regulations.
- strengthening health warnings for cigarettes and smokeless tobacco products
- educating the public about tobacco products and their harms and about FDA's related regulations and other activities
- initiating enforcement actions for violations of the Tobacco Control Act.

Protect the Public Health from the Harmful Effects of Tobacco Use – Center Activities

FY 2012 Enacted Amount: $88,840,496 (All UF)

Public Health Focus

The Tobacco Control Act provides FDA with the authority to regulate the manufacturing, distribution, and marketing of tobacco products based on whether such regulation "will benefit the health of the population as a whole."[1] The Agency's public health goals are to reduce the morbidity and mortality from the use of tobacco products by addressing three principle public health strategic priorities:

- decreasing initiation of tobacco product use,
- decreasing the harms of tobacco products, and
- encouraging cessation among tobacco product users.

Public Health Outcome

FDA is supporting research on the impact of altering nicotine levels in tobacco products to assess how these changes might affect the way people might use those products. In

[1] Section 2 (36) of the Family Smoking Prevention and Control Act (PL 111-31).

addition, FDA will release additional funding announcements in 2012 for the development of research to support many of its regulatory authorities.

FDA has already initiated the first ever longitudinal prospective cohort study of tobacco users in the United States, known as the PATH study (Population Assessment of Tobacco and Health), in collaboration with the National Institutes of Health (NIH)/National Institute of Drug Addiction (NIDA) to better understand the patterns of tobacco use and how it changes over time in adolescents and adults. This longitudinal study will provide a valuable platform for scientific investigations to assess and focus FDA regulatory actions.

In order to determine the effectiveness of the statutory and regulatory requirements on the public health, FDA will continue to conduct evaluation and behavioral research that analyzes the effects of regulatory actions on users and non-users of tobacco products. For example FDA plans to analyze the impact of the new graphic health warning statements on cigarette packaging and in advertisements on consumer perceptions of the harms of tobacco products, interest in quitting and susceptibility to start using tobacco products. FDA will use research and evaluation of the graphic health warnings required to appear on all cigarette packages and advertisements in developing ancillary public education messages.

Given that FDA has expressed the intent to propose regulations to assert jurisdiction over other tobacco products (deeming rule)[2], FDA also plans to support research to assess the impact on public health of new and emerging tobacco products. In particular, FDA plans to support research assessing the constituents, components, and design features of these products, as well as their impact on tobacco use behaviors (including dual- and poly-use of tobacco products) and consumer perceptions about these products.

Promoting Efficiency

The Tobacco Control Act and FDA regulations and guidance documents protect the public health by significantly minimizing the exposure of youth to tobacco products and their marketing by 1) prohibiting the manufacture, distribution, and sales of fruit or candy flavored cigarettes that have special appeal to young people and, 2) by restricting the sales, advertising and promotion of cigarettes, smokeless tobacco products and roll-your-own tobacco to those under the age of 18. Furthermore, FDA is protecting the public health by prohibiting misleading descriptors on tobacco products, and requiring graphic health warnings depicting the harmful effects of smoking on cigarette packs and

[2] The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) provides FDA with the authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The law also permits FDA to issue regulations deeming other “tobacco products,” such as novel products like e-cigarettes or certain dissolvable tobacco products; cigars; pipe tobacco; hookah, etc., to be subject to Chapter IX of the Food Drug & Cosmetic Act (FD&C Act).

in cigarette advertisements. All of these public health-driven regulatory actions are currently being enforced through FDA-funded State- based enforcement programs.

Preventing youth initiation would result in enormous public health benefits. Specifically, the Tobacco Control Act finds that "reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease. Such a reduction in youth smoking would also result in approximately $75 billion in savings attributable to reduced health care costs."[3]

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
280001: Protect the public health by developing and issuing regulations related to tobacco control and limiting access to tobacco products by youth. *(Output)*	FY 2010: Issued regulations protecting the public health from the harmful effects of tobacco use including: prohibiting misleading descriptors, requiring new warning labels on smokeless tobacco products, and the "Reissued 1996 Rule." (Target Met) FY 2010: Initiated and conducted research on the impact of tobacco control regulations. (Target Met) FY 2010 Target: Identify population-based data available to begin assessing impact of tobacco control regulations, their impact on youth and adult access to and use of tobacco products. (Target Met)	Conduct research on how to assess the public health impact of modified risk products, and continue to evaluate the impact of tobacco regulations on the public health. Issue regulations to protect the public health.	Research the impact of changing nicotine levels on product addictiveness and use of products. Through a longitudinal cohort study, monitor the trajectory of tobacco use. Study the impact of reduced levels of toxic harmful/poten-tially harmful constituents on health outcomes. Develop better measures of toxicity appropriate for tobacco, and identify new biomarkers of harm. Carry out on-going	NA

[3] Section 2(14) of the Family Smoking Prevention and Tobacco Control Act (PL 111-31).

			consumer research on the impact of product information (warnings, label claims, descriptors, advertising and marketing) on perceptions of risk and the likelihoods of tobacco use initiation and cessation.	

Tobacco Product Scientific Standard-Setting and Tobacco Product Review – Center Activities
FY 2012 Enacted Amount: $156,455,773 (All UF)

Public Health Focus

In order to protect the public health, the Tobacco Control Act authorizes FDA to conduct or support scientific programs and data collection to provide the data and research to support the development of regulations and guidance documents, and to implement many provisions of the law, including those related to the manufacturing, distribution, sale, and marketing of tobacco products. FDA's scientific, research and data collection/assessment focus on the strategic priorities to implement the Tobacco Control Act of:

- decreasing initiation of tobacco product use;
- decreasing the harms of tobacco products; and
- encouraging cessation among tobacco product users.

Public Health Outcome

FDA is developing improved analytical methods to measure harmful and potentially harmful constituents in order to expand the number of tools available to assess product characteristics. Work is also underway to examine the impact of reduced levels of the identified harmful and potentially harmful constituents as a way to mitigate the morbidity and mortality associated with the use of tobacco products, as well as studying how design features of tobacco products impact tobacco use behavior.

FDA will review public comments received on the list of proposed harmful and potentially harmful tobacco product constituents. FDA will conduct additional research

and revise the list, as appropriate, in order to meet the statutory requirement that the list is understandable and not misleading to a lay person. FDA will use this list to better educate the public about the constituents contained in tobacco products and smoke through appropriate public education and communication programs, as well as assess the impact of this information.

FDA will support the Tobacco Product Scientific Advisory Committee's (TPSAC) work on dissolvable tobacco products. FDA will review the TPSAC report on dissolvables and review additional scientific evidence to determine what regulatory actions, if any, are warranted to protect the public health.

FDA continues to review new tobacco product and modified risk applications in a timely manner, as well as continue its review of the substantial equivalence submissions for products currently on the market.

Promoting Efficiency

FDA has taken a number of science-based regulatory actions as required by law. These include issuing guidance to industry on substantial equivalence. Also, tobacco product manufacturers are reporting the ingredients of each tobacco product by brand and by quantity in each brand and sub-brand. This information helps FDA better understand the products it regulates and promotes efficiency within the FDA Tobacco Program.

Significant program efficiencies accrue to the tobacco industry as well for each of the individual regulatory actions, guidance, or technical assistance documents FDA releases.

FDA achieves these efficiencies by establishing the regulatory framework and processes for FDA review and issuance of marketing orders to industry for new tobacco products, products purported to be modified risk tobacco products, and products proposed to be substantially equivalent to predicate tobacco products. For example:

- FDA provided technical assistance to small tobacco manufacturers to help them understand guidance and regulations related to substantial equivalence. Technical assistance includes information how manufacturers might provide documentation to FDA on predicate products.
- FDA provided flexibility to tobacco manufacturers by allowing them to supplement initial substantial equivalence reports, which allowed companies to continue marketing certain products while FDA conducts substantial equivalence evaluations.
- FDA has issued draft guidance to industry about how to submit new tobacco product applications and plans to issue guidance and/or regulations on tobacco products purported to be modified risk tobacco products. These regulatory

documents provide industry with increased clarify regarding the FDA review processes and expectations.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
280001: Protect the public health by developing and issuing regulations related to tobacco control and limiting access to tobacco products by youth. *(Output)*	FY 2010: Issued regulations protecting the public health from the harmful effects of tobacco use including: prohibiting misleading descriptors, requiring new warning labels on smokeless tobacco products, and the "Reissued 1996 Rule." (Target Met) FY 2010: Initiated and conducted research on the impact of tobacco control regulations. (Target Met) FY 2010 Target: Identify population-based data available to begin assessing impact of tobacco control regulations, their impact on youth and adult access to and use of tobacco products. (Target Met)	Conduct research on how to assess the public health impact of modified risk products, and continue to evaluate the impact of tobacco regulations on the public health. Issue regulations to protect the public health.	Research the impact of changing nicotine levels on product addictiveness and use of products. Through a longitudinal cohort study, monitor the trajectory of tobacco use. Study the impact of reduced levels of toxic harmful/poten-tially harmful constituents on health outcomes. Develop better measures of toxicity appropriate for tobacco, and identify new biomarkers of harm. Carry out on-going consumer research on the impact of product information (warnings, label claims, descriptors, advertising and	NA

			marketing) on perceptions of risk and the likelihoods of tobacco use initiation and cessation.	

<u>Compliance and Regulatory Activities</u> - Center Activities
FY 2012 Enacted Amount: $97,954,376 (All UF)

Public Health Focus

The Tobacco Control Act requires the issuance of regulations and guidance in accordance with certain statutory deadlines. This includes promulgating regulations requiring the testing and reporting of tobacco product constituents, ingredients, and additives by brand and sub-brand. In order to protect the public health, FDA vigorously enforces provisions of the Tobacco Control Act and its implementing regulations.

Public Health Outcome

As required by the Tobacco Control Act, FDA contracts with States and Territories to assist FDA in conducting compliance check inspections of retail establishments. These inspections ensure tobacco product retailers' compliance with "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" and other provisions of the Tobacco Control Act. In FY 2011, FDA provided direct financial support to U.S. States and Territories through the award of approximately $30 million to 37 States and the District of Columbia to conduct compliance check inspections to ensure that tobacco product retailers are complying with the requirements of the Tobacco Control Act. FDA will continue to contract with additional States and Territories and with Tribes and will continue to expand the State Enforcement Program.

FDA will continue to allocate significant resources to enforce statutory requirements of the Tobacco Control Act. FDA will begin enforcing the requirements for graphic health warnings on cigarette packages and in advertisements. This will include the review of cigarette health warning plans submitted by manufacturers. FDA will continue to review new submissions and supplements involving health warning plans for smokeless tobacco products.

As part of its compliance and enforcement program, FDA will continue to conduct routine surveillance, investigation, and evaluation of regulated industry websites that promote and sell tobacco products in the U.S. market. In addition, FDA will continue to monitor the compliance of magazines and publications that contain tobacco advertisements, including those that target youth and minorities.

Promoting Efficiency

The nation's more than 2 million tobacco product retailers are important new partners in FDA's efforts to decrease youth initiation through tobacco product regulations. Retail establishments nationwide are responsible for complying with *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents* and other provisions of the Tobacco Control Act.

To help ensure compliance with these regulations and the law, FDA will continue to provide guidance to industry and retailers to ensure a better understanding of the new law and regulations through CTP's monthly compliance education webinars directed towards tobacco product retailers, which will allow manufacturers and retailers to meet regulatory requirements efficiently and effectively as possible. FDA will also assist tobacco retailers to appreciate their role in protecting America's youth from initiation and use of tobacco product use as required by the Tobacco Control Act.

FDA established the Office of Small Business Assistance in the Center for Tobacco Products to assist small tobacco product manufacturers and retailers comply with the Tobacco Control Act. The Office has a dedicated webpage, e-mail address, and staff to assist small businesses with their questions, comments, and concerns. Additionally, the Office provides educational webinars and training for small tobacco product businesses. Examples of webinar topics include compliance with the requirements related to the new graphic cigarette health warnings on packaging and in advertising and FDA's guidance on new tobacco product applications.

This enforcement and compliance program also significantly increased efficiencies by providing a uniform framework for FDA enforcement through a robust training program for credentialed State and Territorial officials. Additionally, CTP implemented a mobile device inspection tool using customized software known as the Tobacco Inspection Management Systems (TIMS) Mobile Application. The tool eliminates the need to mail, fax, or scan paper forms to and from field inspectors, and eliminates days of data entry thereby decreasing the time for conducting and reviewing inspections and gathering evidence.

Compliance and Regulatory Activities - Field Activities
FY 2012 Enacted Amount: $6,250,000 (All UF)

Public Health Focus

In order to ensure compliance with the Tobacco Control Act, FDA conducts surveillance, investigations, inspections, sample collections, and detention of tobacco products . Among other provisions, the law bans the manufacture, distribution or marketing of cigarettes with fruit or candy characterizing flavors, with the exception of menthol.

In FY 2011, the FDA Office of Regulatory Affairs (ORA) began work to establish a testing laboratory with expertise and capacity to analyze tobacco products. The ORA laboratory will acquire tobacco-specific testing equipment such as smoking machines and will complete assignments requested by CTP which may include testing cigarettes and/or other tobacco products for flavor compounds, other potentially harmful constituents and future tobacco product standards. Concurrently, ORA is collaborating with the Alcohol and Tobacco, Tax and Trade Bureau and CTP on method development and validation studies to expand analytical capabilities to additional harmful chemical ingredients and constituents. In addition, ORA's Forensic Chemistry Center laboratory will be providing support to the Office of Criminal Investigations (OCI) related to the identification and characterization of counterfeit cigarettes.

In FY 2012, ORA began inspections of registered tobacco product establishments to determine their compliance with the Tobacco Control Act. These include registration, product and ingredient listing, packaging, labeling, and advertising requirements, and marketing authorization for new or modified risk tobacco products,

Public Health Outcome

ORA carries out a multi-tiered approach towards enforcing the requirements of the Tobacco Control Act. For example, working with CTP, ORA issued import bulletins relating to the restrictions on the terms "low," "mild," and "light" to describe tobacco products and for prohibited candy or fruit flavored cigarettes. This required increased surveillance of imported tobacco products at the borders ensures that imported tobacco products are not adulterated and conform to the same regulatory requirements as domestically-manufactured cigarettes.

Promoting Efficiency

ORA will continue to engage in these enforcement activities, which could include laboratory-based support for enforcement actions to ensure that industry complies with the Tobacco Control Act and its regulations. Specific examples of program efficiencies that may flow from these activities include development and promulgation of standards for laboratory testing, such as for harmful and potentially harmful ingredients of tobacco products. Once developed and promulgated, these laboratory and testing standards will create a uniform set of methods and standards by which the tobacco manufacturers can analyze their products in an efficient and targeted manner. Thus, the tobacco industry will avoid inefficient use of its resources for broad or unnecessary product testing.

ORA has begun the process of developing a trained cadre of investigators to perform tobacco manufacturer inspections. ORA and CTP have identified the establishments to be inspected and ORA is collaborating with CTP to develop and present training to ORA investigators. By using a cadre approach to conducting these types of inspections, ORA will develop a staff of investigators who are well trained in tobacco regulation, policy and inspection techniques.

ORAs tobacco commissioning program further increases the efficiency in which FDA can share information with State and local agencies. This program is modeled on the traditional food and drug commissioning process and allows inspections to be completed by States on behalf of FDA. As of the end on FY 2011, officials have been commissioned in 37 states and one U.S. territory in support of contracts with FDA to conduct retail tobacco inspections.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
280005: Total number of compliance check inspections of retail establishments in States under contract. *(Outcome)*	FY 2011: 24,419 (Historical Actual)	84,000	150,000	+66,000

Tobacco Product Health Communication and Education – Center Activities

FY 2012 Enacted Amount: $105,250,355 (All UF)

Public Health Focus

As required by statute, FDA is promoting the public health by leading comprehensive, science-based communication and outreach efforts to protect and educate the nation about the dangers of tobacco products. All aspects of FDA's three strategic priorities (decreasing initiation of tobacco product use, decreasing the harms of tobacco products, and encouraging cessation among tobacco product users) have important public health education and communication components with respect to implementing the Tobacco Control Act.

Public Health Outcome

The Tobacco Control Act authorizes FDA to educate the public about tobacco products and their dangers. FDA will communicate broadly and effectively to the general public and to priority audiences about tobacco product content and their harms. Specifically, FDA will:

- Develop comprehensive youth and young adult prevention campaigns educating these audiences about the harms of tobacco use and the potential for addiction as required by the Tobacco Control Act;
- Support the HHS-wide effort to communicate accurate and effective messages about tobacco products FDA regulates and describe the harms resulting from

their use to distinct audiences, including the media, opinion makers and stakeholders;
- Design an evaluation program to demonstrate effectiveness of communication programs and to measure changes in attitudes and behaviors toward tobacco product usage over time

For example, FDA is currently educating retailers and the public about "Regulations to Restrict the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" and about the restrictions on use of misleading descriptors such as "light," "low," and "mild" on tobacco product packaging or in advertisements.

In enacting the Tobacco Control Act, Congress found that in 2005, cigarette manufacturers spent more than $13 billion to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use. Therefore, as required by FDA's "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Children and Adolescents", the Agency will continue its health education efforts to reduce perceived attractiveness and access of tobacco products to youth, and provide users with the information needed to understand the harms of tobacco products and tobacco use.

In addition, FDA continues to engage all stakeholders about the Tobacco Control Act and how to comply with its requirements. Specifically, FDA is providing "Break the Chain of Tobacco Addiction" educational and display materials at no charge to U.S. retailers to promote compliance with the law. The materials were developed with input from retail establishments and include posters, flyers, and syndicated content for retailer websites. FDA is also creating customized tools that enable the public and other stakeholders to better access and understand the TCA in a plain language format. This includes plain language summaries, interactive timelines, and customized searches by audience, type of tobacco product, and topic.

Promoting Efficiency

The Tobacco Control Act requires FDA to inform the nation about the harmful and potentially harmful constituents of tobacco products which in turn will increase public understanding about the dangers of tobacco. The public health impact will be a decrease in the enormous economic toll from health care costs and lost productivity from the many diseases caused by tobacco use.

The implementation strategy for all public education campaign materials developed, including research studies, will include sharing this public education information among stakeholders, thereby greatly leveraging FDA resources and amplifying the Agency's message to local communities.

FDA also is launching a "Tobacco Regulations 101" education campaign for various stakeholders to help promote understanding of how regulations are issued, identify

opportunities for involvement in the regulatory process, and provide information about public dockets, notice and comment rulemaking activities, etc

Performance Measures

The following table lists the performance measures associated with this subprogram.

	Most Recent Result		FY 2013	
280004: Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use. *(Output)*	FY 2010: First ever retailer education program was implemented, including PR, direct mail, web updates and educational webinars. In addition a media outreach strategy was developed to proactively communicate tobacco related public health messages to the general public. FY 2011 Target: Implement and refine education program directed to retailers and the general public, especially youth. (Target Met)	Continue to implement and improve programs designed to educate the public and industry.	Continue to implement and improve programs designed to educate the public and industry. Expand consumer health education on prevention and cessation.	NA

Information Technology Investments –Tobacco Program Activities (FY 2012 Enacted Amount displayed as a non-add item: $21,818,276)

FDA modernized and enhanced its information technology (IT) infrastructure to provide a state of the art, secure technological foundation to support all FDA programs. This newly completed effort provides a foundation on which FDA may improve its capabilities and enhance its ability to perform its scientific and regulatory mission. FDA's agency-wide costs associated with the operation and maintenance of this shared IT infrastructure includes two data centers, telecommunication networks, IT security and help desk functions. In addition, each center and office has program specific IT systems and is supported by enterprise systems ranging from improving the premarket review process for all regulated products to post-market surveillance, including adverse event detection, and future scientific computing capabilities This common infrastructure

facilitates consolidation and meets E.O.13514 related to energy efficiency, HHS and OMB mandates with respect to green computing, cloud computing, and virtualization.

In order to implement the Tobacco Control Act, FDA has leveraged existing IT systems supporting Foods and Medical Product programs to provide an electronic solution to regulate the manufacture, distribution and sale, and content of tobacco products. As a specific example, FDA has developed an electronic submission tool, eSubmitter, to streamline submission and receipt of registration and product listing information required by section 905 of the act. CTP also plans, assigns, and tracks regulatory activities for state compliance check inspections of retails using the newly-created Tobacco Inspection Management System (TIMS). With such information management technologies, the FDA will be able to regulate tobacco products with transparency, collaboration, knowledge management, agility and improved efficiency.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) program levels from FY 2008 through FY 2012.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2008 Actual	N/A	N/A	N/A	N/A
2009 Actual	$4,908,000	$4,908,000	$0	0
2010 Actual	$64,418.000	$0	$64,418,000	90
2011 Actual	$136,225,000	$0	$136,225,000	236
2012 Enacted	$454,751,000	$0	$454,751,000	392

Summary of the Budget Request

The FY 2013 budget request for the FDA Tobacco Act Program is $482,398,000 for an increase of $27,647,000 above the FY 2012 Enacted Budget. The Center for Tobacco Products amount is $472,998,000 supporting 471 FTE. The Field amount is $9,400,000, supporting 40 FTE.

The amount requested in the FY 2013 budget is authorized by the Tobacco Control Act and comprise entirely of tobacco user fees. The Tobacco Control Act requires that these user fees may only be used for FDA tobacco regulatory activities. Conversely, the law prohibits the use of non-tobacco funds for FDA tobacco regulatory activities.

Protect the Public Health from the Harmful Effects of Tobacco Use

Center Activities (FY 2012 Enacted Amount: $88,840,496)
FY 2013 increase above FY 2012 Enacted: +$6,081,504; 31 FTE

The Tobacco Control Act provides FDA with the authority to protect the public health by initiating actions to regulate tobacco products addressing issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco. In addition, FDA is to set national standards controlling the manufacture of tobacco products, regulate the levels of tar, nicotine, and other harmful components of tobacco products, and to ensure that consumers are better informed by requiring tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products.

The foundation of science upon which tobacco product regulation is being built will continue to expand in FY 2013. FDA will collect the first wave of data in FY 2013 in the ground-breaking Population Assessment of Tobacco and Health Study (PATH). PATH is a national, prospective, longitudinal cohort study funded by FDA to involve more than 40,000 tobacco users. PATH is designed to provide better understanding of the patterns of tobacco use and how it changes over time in adolescents and adults. This longitudinal study will also provide a valuable platform for additional scientific investigations to assess and focus FDA regulatory action.

In FY 2013 FDA will continue and expand funding for biomedical research collaborations within FDA and with NIH and CDC in the areas of tobacco product addictiveness, tobacco product chemistry and engineering related to abuse liability thresholds, measurement and standards for assessment of harmful ingredients, biomarkers for health effects of exposure to tobacco ingredients, cognitive and behavioral determinants of tobacco initiation/maintenance and cessation related to marketing and health warnings, and building the foundation of knowledge of the chemistry, toxicology, health and public health impact of new and emerging tobacco products.

Additionally, in FY 2013, CTP will continue to invest in building the cadre of regulatory science leaders needed to address tobacco product regulation today and into the future. FDA will expand the FDA Tobacco Regulatory Science Fellowship Program in conjunction with the National Academy of Sciences, Institute of Medicine and initiate a research training grant program in conjunction with NIH using the National Research Service Award (NRSA) grant mechanism. The multi-year NRSA grants will support a broad array of scientific disciplines from basic and physical sciences to clinical and social sciences research. These programs will insure that there is a diverse pool of highly trained professionals available to address the tobacco regulatory science needs well into the future both by attracting mid-career and experienced professionals to move into tobacco product regulatory science as well as to attract young investigators into tobacco regulatory science research at different stages in their research careers.

In FY 2013 FDA fully intends to implement additional provisions of the Tobacco Control Act by drafting and issuing regulation and guidance documents to protect and improve the public health. As required by the Tobacco Control Act, FDA intends to publish a regulation that requires testing and reporting of tobacco product constituents, ingredients and additives, including smoke constituents, by brand and sub-brand.

Finally, in FY 2013, FDA intends to develop a regulation specifying how tobacco product manufacturers must provide market share information to FDA which will then be used to calculate tobacco user fees. The Tobacco Control Act requires the transfer of the calculation of user fees from the Department of Agriculture to FDA by FY 2014. User fees support all activities undertaken by FDA related to tobacco regulation.

Tobacco Product Scientific Standard-Setting and Tobacco Product Review

Center Activities (FY 2012 Enacted Amount: $156,455,773)
FY 2013 increase above FY 2012 Enacted: +$4,589,227; 3 FTE

FDA's tobacco product regulatory and public health goals are guided by the scientific data developed and evaluated by CTP. This scientific knowledge is required for FDA's regulatory activities and the Agency's review of tobacco products.

In FY 2013, FDA will continue review of regulatory submissions from the tobacco industry, including Substantial Equivalence Reports and requests for Substantial Equivalence Exemptions as well as New Tobacco Product applications.

As new products emerge, including those making modified risk claims, FDA is required to evaluate them based on a population health standard that analyzes the impact of that product on both tobacco product users and non-users. FDA is also required to study the public health impact when consumers switch from conventional to new and emerging tobacco products and conduct research to explore the motivation for users and non-users to initiate use of these products.

FDA will continue and expand its research base in order to study issues relevant to scientific standards and authorities for evaluation of tobacco products proposed to be marketed with a modified risk claim. Marketing of modified risk tobacco products is authorized under the Tobacco Control Act if FDA determines that such products have the potential to reduce the burden of tobacco-related disease, death, and disability in our nation.

Also, in FY 2013 FDA will publish a harmful and potentially harmful tobacco product constituent (HPHC) list that will provide the public with critically important new information about the content of tobacco products. The HPHC list will be published by brand and sub-brand.

Compliance and Regulatory Activities

Center Activities (FY 2012 Enacted Amount: $97,954,376)
FY 2013 increase above FY 2012 Enacted: +$6,189,624; 32 FTE

In FY 2013, FDA will continue its expansion of the State Retail Enforcement Program. This work includes re-awarding contracts to U.S. States and Territories that are already under contract with FDA to conduct compliance check inspections of retail establishments that sell tobacco products. FDA will also begin awarding contracts to Tribal Nations to assist in conducting compliance check inspections of retail establishments on tribal lands as envisioned in the Tobacco Control Act. These compliance check inspections help FDA enforce provisions of the Tobacco Control Act and regulations.

The State Retail Enforcement Program has several other associated activities that will begin or continue in FY 2013, including:

- Increasing the total number of inspections of tobacco retailers within U.S. States and Territories.
- Conducting quality assessment of performance under the State contracts.
- Maintaining effective internal controls that meet the objectives of the Federal Managers' Financial Integrity Act to ensure effective and efficient operations and compliance with applicable laws and regulations.
- Continuing to issue Warning Letters and initiating Civil Money Penalty actions, and other applicable enforcement actions against retailers that violate the law and applicable regulations.
- Include newly-deemed tobacco products in the State Retail Enforcement Program.

However, CTP's efforts to ensure compliance with the law are not limited to enforcement efforts. To encourage voluntary compliance, CTP will continue to educate retailers about their responsibilities to protect the Nation's young people as required by the Tobacco Control Act. These efforts will include outreach to small businesses and to those in minority communities. CTP plans to hold monthly compliance education webinars during which retailers will be provided with an opportunity to ask questions about FDA regulatory activities and provide feedback to CTP's Office of Compliance and Enforcement on topics to include in future compliance webinars. CTP will also hold quarterly compliance education webinars directed towards small manufacturers to provide information about the Tobacco Control Act, FDA regulations and other activities, including what to expect during an FDA inspection of a manufacturing facility.

Field Activities (FY 2012 Enacted Amount: $6,250,000)
FY 2013 increase above FY 2012 Enacted: +$3,150.000; 14 FTE

FDA will work to expand inspections, investigations and surveillance of tobacco product manufacturers, distributors, wholesalers, and importers in FY 2013. FDA's Office of Regulatory Affairs will conduct inspections of tobacco product manufacturers to ensure

their compliance with the laws. These inspections will determine whether a company is properly submitting registration, product and ingredient listing information, complying with the packaging, labeling and advertising requirements, and other statutory and regulatory requirements.

There are several other activities associated with expanding inspections, investigations and surveillance of tobacco product manufacturers, distributors, wholesalers, and importers that FDA will initiate or continue in FY 2013 including:

- Utilizing the FDA laboratory that tests, evaluates, and processes regulatory samples of tobacco products that will be used to support enforcement actions.
- Expand internet surveillance and investigation of tobacco product manufacturers, distributors and retailers to ensure their packaging, labeling, marketing, and advertisements of tobacco products is in compliance with the laws.
- Continue to send Warning letters and initiate other enforcement actions for violations identified.

Tobacco Product Health Communications and Education

Center Activities (FY 2012 Enacted Amount: $105,250,355)
FY 2013 increase above FY 2012 Enacted: +$7,636.645; 39 FTE

Directly related to FDA's tobacco product regulatory authorities, FDA will continue to educate the public about tobacco products and their harms in FY 2013. Specifically, FDA plans to develop several public health education campaigns related to FDA's mandate to educate the public about harmful and potentially harmful constituents of tobacco products; the statutory requirement to require health warnings on cigarettes and smokeless tobacco products packages and in advertising; restrictions on marketing and sales of tobacco products to youth; use of misleading descriptors like "light," "low," and "mild" on tobacco products; and other FDA regulatory authorities as they are implemented. Examples of these public health education programs include:

- Development of comprehensive youth and young adult public health education programs designed to inform them about the harms of tobacco use and the potential for addiction;
- Development of comprehensive youth and young adult public health education programs about the benefits of tobacco cessation in reducing the harms of tobacco use;
- Support for a HHS-wide effort to provide accurate messages about tobacco products and the harms resulting from their use; and
- Development of a comprehensive benchmark and tracking evaluation program that will assess the effectiveness of FDA public health education programs.

CTP Performance Activity Data (PAD)

The following table lists the CTP Program Activity Data (PAD) over a three year fiscal period.

CTP Workload and Outputs	FY 2011 Actual	FY 2012 Enacted	FY 2013 Estimate
Administrative/Management Support			
Workload			
Number of Advisory Committee Meetings	7	4	6
Number of Warning Letters Issued	1,024	2,500	3,900
Percentage of Tobacco User Fees Collected	99%	99%	99%